

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA and STATE
OF NEW YORK *ex rel.* Yitzchok Zylberberg,

Plaintiffs,

MEMORANDUM AND ORDER

v.

19-CV-4239 (RPK) (SJB)

MAIMONIDES MEDICAL CENTER and
MMC PHARMACY, INC.,

Defendants.

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RACHEL P. KOVNER, United States District Judge:

Relator Yitzchok Zylberberg filed this *qui tam* action, claiming that defendants violated the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and the New York False Claims Act, N.Y. State Fin. Law § 187 *et seq.*, because defendant Maimonides Medical Center steered patients to defendant MMC Pharmacy, Inc. in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and the Physician Self-Referral Law (“Stark Law”), 42 U.S.C. § 1395nn. Defendants move to dismiss the complaint. For the reasons explained below, the motion is granted, and the complaint is dismissed with prejudice.

BACKGROUND

The following facts are taken from the second amended complaint and are assumed to be true for purposes of this order.

Relator’s challenge concerns a “med-to-beds” program operated by defendants Maimonides Medical Center and MMC Pharmacy. *See* Second Am. Compl. (“SAC”) ¶¶ 14–25 (Dkt. #29); Mem. in Supp. of Mot. to Dismiss 1 (Dkt. #53) (describing the program as a “med-to-beds” program); Mem. in Opp’n to Mot. to Dismiss 8 (Dkt. #54) (same nomenclature).

Maimonides Medical Center is a hospital located in Kings County, New York. SAC ¶ 9. MMC Pharmacy is a pharmacy located on property that is owned and used exclusively by the Medical Center. *Id.* at ¶¶ 10–11. “Upon information and belief,” MMC Pharmacy “is owned and/or controlled by” the Medical Center. *Id.* at ¶ 11. Relator worked for the Medical Center as a pharmacist between 1992 and 2019. *Id.* at ¶¶ 12–13.

In the program that relator challenges, defendants arranged for MMC Pharmacy to deliver medications to patients who were being treated at the Medical Center, thereby enabling the patients to obtain their medicines at the Medical Center itself, upon discharge from the hospital. *Id.* at ¶¶ 14–15. Pharmacists at the Medical Center would also provide discharge counseling to patients regarding medications that had been dispensed by MMC Pharmacy. *Id.* at ¶ 17A. Upon relator’s information and belief, a majority of discharged patients received medications in this way, and many used Medicare and Medicaid to pay for their medications. *Id.* at ¶¶ 14, 17A, 20. Other retail pharmacies were not given similar access to discharged patients at the Medical Center, and relator did not observe patients being given the choice of obtaining their post-discharge prescriptions from other pharmacies. *Id.* at ¶ 19.

The Medical Center occasionally directed relator to provide discharge counseling to patients who received their medications from MMC Pharmacy. *Id.* at ¶ 17. “After performing this service on several occasions,” relator “objected to providing such counseling, voicing concerns that it was improper for the Hospital to steer its patients to MMC Pharmacy and that the MMC Pharmacy pharmacists who are dispensing such medications are obligated to provide such counseling to the discharged outpatients.” *Ibid.* The Medical Center then stopped requiring relator to provide MMC Pharmacy medications to these discharged patients, or to provide counseling to

them about MMC Pharmacy medications, but continued to assign other pharmacists at the Medical Center to do so. *Ibid.*

Relator filed this lawsuit in July 2019, filed an Amended Complaint in October 2019, and filed a Second Amended Complaint in December 2021. *See generally* Compl. (Dkt. #1); First Am. Compl. (Dkt. #4); SAC. The Second Amended Complaint asserts *qui tam* claims under the False Claims Act and the New York False Claims Act, SAC ¶¶ 26–31, in addition to certain other claims that relator has dismissed voluntarily. *See* SAC ¶¶ 32–42; July 5, 2022 Letter 3 (Dkt. #47).

Both the United States and New York declined to intervene. *See* Not. of Election to Decline Intervention (Dkt. #31).

Defendants move to dismiss the Second Amended Complaint for failure to state a claim. Relator opposes the motion and “attached a proposed Third Amended Complaint . . . just in case the Court rules that” the Second Amended Complaint fails to state a claim. Mem. in Opp’n to Mot. to Dismiss 24; *see* Proposed Third Am. Compl. (Dkt. #54-1).

STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 12(b)(6), a defendant may move to dismiss a complaint based on “failure to state a claim upon which relief can be granted.” To avoid dismissal on that basis, a complaint must plead “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (discussing Fed. R. Civ. P. 8). The facial “plausibility standard is not akin to a ‘probability requirement.’” *Ibid.* (quoting *Twombly*, 550 U.S. at 556). But it requires a plaintiff to allege sufficient facts to enable the court to “draw the reasonable inference that the defendant is liable for

the misconduct alleged.” *Ibid.* In evaluating a motion to dismiss under Rule 12(b)(6), the court must accept all facts alleged in the complaint as true. *Ibid.* But it need not adopt “[t]hreadbare recitals of the elements of a cause of action” that are “supported by mere conclusory statements.” *Ibid.*

Claims brought under the False Claims Act are subject to the heightened pleading standard of Federal Rule of Civil Procedure 9(b), which provides that “a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” Fed. R. Civ. P. 9(b); *see Gold v. Morrison-Knudgson Co.*, 68 F.3d 1475, 1477 (2d Cir. 1995). “To satisfy this Rule, a complaint alleging fraud must ‘(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.’” *United States ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 25 (2d Cir. 2016) (quoting *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1128 (2d Cir. 1994)). “Claims under the [False Claims Act] analogues,” such as the New York False Claims Act, “must also satisfy Rule 9(b).” *United States ex rel. Hart v. McKesson Corp.*, 602 F. Supp. 3d 575, 585–86 (S.D.N.Y. 2022).

DISCUSSION

The motion to dismiss is granted.

The False Claims Act prohibits “knowingly present[ing] . . . a false or fraudulent claim for payment or approval,” 31 U.S.C. § 3729(a)(1)(A), “to an officer, employee, or agent of the United States,” *id.* § 3729(b)(2)(A)(i). *See Kellogg Brown v. Root Servs., Inc. v. U.S., ex rel. Carter*, 575 U.S. 650, 653 (2015). “A claim is false within the meaning of the [False Claims Act] if it ‘falsely certifies compliance with a . . . statute, regulation or contractual term,’” *United States ex rel. Ladas*

v. Exelis, Inc., 824 F.3d 16, 26 (2d Cir. 2016) (citation omitted), and the misrepresentation is “material to the Government’s payment decision,” *Bishop v. Wells Fargo & Co.*, 870 F.3d 104, 107 (2d Cir. 2017) (citation omitted). Likewise, “[w]hen . . . a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant’s representations misleading with respect to the goods or services provided.” *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 187 (2016). The New York False Claims Act “mirrors the federal [False Claims Act], and New York courts look to federal law to interpret the state statute.” *United States ex rel. Pelullo v. Am. Int’l Grp., Inc.*, 757 F. App’x 15, 17 (2d Cir. 2018) (citing *State of New York ex rel. Seiden v. Utica First Ins. Co.*, 943 N.Y.S.2d 36, 39 (App. Div. 2012)).

Here, relator alleges that defendants are liable under the False Claims Act and the New York False Claims Act on the theory that defendants sought Medicare and Medicaid reimbursements while either expressly or impliedly representing that they were in compliance with relevant statutes while, in relator’s view, defendants were in fact violating the Anti-Kickback Statute and the Stark Law.¹ SAC ¶¶ 25, 27, 30. But as explained below, relator has not plausibly alleged a violation of either statute. Accordingly, relator has not plausibly alleged that defendants made false or fraudulent claims for payment or approval based on false certifications of compliance with the law. The motion to dismiss is therefore granted. Further, because relator’s proposed

¹ Relator argues in his memorandum of law in opposition to the motion to dismiss that “Defendants violated the Anti-Kickback Statutes (‘AKS’), the Stark Laws, the New York Public Health Law and other laws.” Mem. in Opp’n to Mot. to Dismiss 6–7. Because relator’s False Claims Act and New York False Claims Act claims do not allege predicate violations of the New York Public Health Law or “other laws,” see SAC ¶¶ 27, 30, and the parties have not briefed those issues, see generally Mem. in Supp. of Mot. to Dismiss (Dkt. #53); Mem. in Opp’n to Mot. to Dismiss, the Court does not consider those alleged violations here. See *Williams v. Rosenblatt Secs. Inc.*, 136 F. Supp. 3d 593, 609 (S.D.N.Y. 2015) (“A plaintiff cannot amend his complaint in [a] response to a motion to dismiss.”); *Mathie v. Goord*, 267 F. App’x 13, 14 (2d Cir. 2008).

Third Amended Complaint fails to cure the deficiencies outlined in this Order, leave to amend is denied.

I. Relator Has Not Plausibly Alleged a Violation of the Anti-Kickback Statute

Relator has not plausibly alleged that defendants violated the Anti-Kickback Statute. That statute prohibits “knowingly and willfully” offering, soliciting, receiving, or paying “any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . . in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program.” 42 U.S.C. §§ 1320a-7b(b)(1)–(2). The term “remuneration” is defined as “transfers of items or services for free or for other than fair market value,” *id.* § 1320a-7a(i)(6), and courts have found that the term has an “expansive scope,” *State v. MedImmune, Inc.*, 342 F. Supp. 3d 544, 552–53 (S.D.N.Y. 2018) (collecting cases).

Relator’s theory is that defendants’ meds-to-beds program violated the Anti-Kickback Statute because the Medical Center has a financial interest in MMC Pharmacy. Specifically, relator contends that because the Medical Center “owns and/or has a financial interest in MMC Pharmacy,” the Medical Center “received substantial amounts of revenue on account of” using MMC Pharmacy for patients’ prescriptions, SAC ¶ 22, which, in relator’s view, means that the Medical Center received “remuneration . . . for referring” patients to MMC Pharmacy, 42 U.S.C. § 1320a-7b(b)(1)–(2). *See* Mem. in Opp’n to Mot. to Dismiss 8–10. In relator’s view, “while it is permissible, and may even be preferable, for an in house pharmacy to deliver pharmaceuticals directly to patients being discharged from the hospital” when the pharmacy is part of the hospital, “in our case such meds-to-beds program is illegal because the Hospital is steering the business to a different entity, the offsite Pharmacy, in which it has a financial interest.” *Id.* at 9. Defendants

vigorously dispute this theory, arguing that “a corporate relationship between two entities who refer one another patients does not render the referrals unlawful.” Reply in Supp. of Mot. to Dismiss 2 (Dkt. #55).

But even assuming *arguendo* that financial links between the Medical Center and MMC Pharmacy mean that MMC Pharmacy provided remuneration to the Medical Center to induce referrals of federal and state health care program business, relator’s allegations nevertheless fail to state a claim because relator has not plausibly alleged that defendants acted with the requisite mental state. “[A] person must ‘knowingly and willfully’ provide prohibited remuneration to be liable” under the Anti-Kickback Statute, “which means she must have offered the payment with the intent to violate a known legal duty.” *Pfizer, Inc. v. U.S. Dep’t of Health and Human Servs.*, 42 F.4th 67, 79 (2d Cir. 2022); see *United States ex rel. Hart v. McKesson Corp.*, No. 15-CV-903 (RA), 2023 WL 2663528, at *7 (S.D.N.Y. Mar. 28, 2023). In other words, “to satisfy the [Anti-Kickback Statute’s] scienter requirement, [a relator] must plead facts that give rise to a plausible inference that [a defendant] knew its conduct was unlawful.” *Hart*, 2023 WL 2663528, at *7 (citation omitted). “[B]ecause Federal Rule of Civil Procedure 9(b) allows ‘conditions of a person’s mind [to] be alleged generally,’ the plaintiff may allege that the defendant acted willfully ‘through circumstantial evidence . . . e.g., proof that a defendant took several actions inconsistent with a good-faith belief that his conduct was legal.’” *United States v. Novartis AG*, No. 04-CV-4265 (NGG) (RLM), 2011 WL 13234720, at *9 (E.D.N.Y. Feb. 8, 2011) (citation omitted).

The Second Amended Complaint does not plausibly allege that defendants acted with knowledge that their conduct was unlawful. Its only allegation going to this element is that relator “voic[ed] concerns that it was improper for the Hospital to steer its outpatients to MMC Pharmacy” and that “[o]n account of his complaint, the Hospital no longer required Mr. Zylberberg to continue

providing MMC Pharmacy medications to outpatients.” SAC ¶ 17. But this allegation that relator criticized the meds-to-beds program with MMC Pharmacy as “improper,” without more, does not plausibly suggest that defendants themselves believed their conduct violated a known legal duty. *See, e.g., Hart*, 2023 WL 2663528, at *9 (“[A]llegations about things that [relator] said to other sales employees within the company, without more, does not establish what [the company] believed about offering the business tools to oncology practices. But even if the Court were to credit Hart’s allegations as somehow speaking to the company’s knowledge, beliefs about the ‘inappropriate’ or ‘unethical’ nature of providing the business tools is, without more, insufficient to adequately plead purported knowledge of *unlawfulness*—let alone an ‘intentional violation of a known legal duty.’”) (quoting *Pfizer*, 42 F.4th at 77); *United States ex rel. Fitzer v. Allergan, Inc.*, No. 17-CV-668 (SAG), 2021 WL 4133713, at *7 (D. Md. Sept. 10, 2021) (concluding that “the fact that relator told Allergan that he believed the physician locator violated the [Anti-Kickback Statute]” did not “indicate[] that Allergan was acting with malintent”).

No more persuasive is relator’s argument that “it is obvious that the Hospital and the Pharmacy, which are sophisticated and prominent entities in the health care field, would be aware of the illegality of steering patients in violation of the [False Claims Act].” Mem. in Opp’n to Mot. to Dismiss 23. Relator falls far short of showing that defendants’ conduct was so “obvious[ly]” a violation of the Anti-Kickback Statute that scienter can be inferred from their mere “sophisticat[ion]” as entities in the health care field. *Ibid.* And the complaint “lack[s] specific allegations of the type that other courts have found to support a plausible inference of knowledge that the conduct was unlawful, such as actions taken to conceal the fraudulent scheme,” “notice from counsel that the program may be unlawful,” “cancellation of the program due to concerns

over its lawfulness,” “or a service without legitimate value that was a pretext to provide remuneration.” *Hart*, 2023 WL 2663528, at *10 (collecting cases).

II. Relator Has Not Plausibly Alleged a Violation of the Stark Law

Relator has not plausibly alleged a violation of the Stark Law, either. The statute provides that “if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then . . . the physician may not make a referral to the entity for the furnishing of designated health services.” 42 U.S.C. § 1395nn(a)(1)(A). By its plain terms, the statute prohibits only referrals involving physicians (or their immediate family members). Because the defendants are businesses—not physicians—relator has not plausibly alleged that either defendant violated the Stark Law. *See, e.g., Aero Med, Inc. v. White Mountain Communities Hosp., Inc.*, No. 11-CV-8031 (PHX) (GMS), 2012 WL 4086531, at *4 n.3 (D. Ariz. Sept. 17, 2012) (“[T]he Stark Anti-Referral Law prohibits physicians from referring patients to entities in which the physician has a financial interest. 42 U.S.C. § 1395nn(a) (2012). It is inapplicable here because [White Mountain Regional Medical Center] is not a physician.”); *Brown v. Tethys Bioscience, Inc.*, No. 10-CV-1245, 2013 WL 65456, at *10 (S.D. W. Va. Jan. 4, 2013) (“By its plain terms, the Stark Act applies to physician referrals. Weiss does not even attempt to provide a rationale as to how the section of the Stark Act cited by her, 42 U.S.C. § 1395nn(a)(1), should apply in this case given that neither she nor Tethys is a physician.”) (internal citation omitted); *United States v. Razalan*, 725 F. Supp. 2d 636, 641 (E.D. Mich. 2010) ([T]he self-referral ban applies only to physicians.”); *United States ex rel. Roberts v. Aging Care Home Health, Inc.*, No. 02-CV-2199, 2008 WL 2945946, at *8 (W.D. La. July 25, 2008) (“Mr. Davis argued, and the Government concedes, that only physicians . . . can violate the Stark Statute.”).

III. The Complaint Is Dismissed With Prejudice

The complaint is dismissed with prejudice. In general, “[l]eave to amend a complaint ‘shall be freely given when justice so requires,’” *Parker v. Columbia Pictures Indus.*, 204 F.3d 326, 339 (2d Cir. 2000) (quoting Fed. R. Civ. P. 15(a)), but “[l]eave may be denied ‘for good reason, including futility.’” *TechnoMarine SA v. Giftports, Inc.*, 758 F.3d 493, 505 (2d Cir. 2014) (citation omitted). “When the plaintiff has submitted a proposed amended complaint, the district judge may review that pleading for adequacy and need not allow its filing if it does not state a claim upon which relief can be granted.” *Ricciuti v. N.Y.C. Transit Auth.*, 941 F.2d 119, 123 (2d Cir. 1991).

Relator’s proposed third amended complaint fails to cure the scienter deficiencies identified in this Order. The proposed complaint’s only additional allegation going to defendants’ state of mind is that “[d]efendants knew, or acted recklessly in not knowing, that it was illegal for the Hospital to steer patients to its affiliated pharmacy, MMC Pharmacy.” Proposed Third Am. Compl. ¶ 22E. This allegation is “conclusory and not entitled to be assumed true,” *Iqbal*, 556 U.S. at 671; *see ibid.* (disregarding an allegation that defendants “‘knew of, condoned, and willfully and maliciously agreed to subject [plaintiff]’ to harsh conditions of confinement”), and so the proposed complaint fails to state a plausible violation of the Anti-Kickback Statute for the reasons already discussed. Likewise, the proposed complaint does not—and could not—include any allegations showing that the Stark Law applies to defendants. And while relator requests leave to file a *fourth* proposed amended complaint “if the Court rules that additional changes besides what is included in the proposed Third Amended Complaint are needed,” Mem. in Opp. to Mot. to Dismiss 24, leave is denied because relator was on notice of the identified deficiencies and failed to cure them in the proposed Third Amended Complaint, *see* Mem. in Supp. of Mot. to Dismiss

16–17 (arguing that scienter is inadequately pleaded); *id.* at 10 (arguing that the Stark Law does not apply to defendants).²

CONCLUSION

The motion to dismiss is granted, and the complaint is dismissed with prejudice.

SO ORDERED.

/s/ Rachel Kovner

RACHEL P. KOVNER

United States District Judge

Dated: September 27, 2023
Brooklyn, New York

² The proposed Third Amended Complaint raises two new legal theories that were not included in the Second Amended Complaint. Specifically, it alleges that defendants violated the False Claims Act and the New York False Claims Act based on alleged violations of New York Public Health Law Section 238-a (prohibiting certain referrals between health-care providers) and New York State Education Law Section 6530(17) (prohibiting the exercise of undue influence on patients for financial gain). *See* Proposed Third Am. Compl. ¶¶ 1, 28–29, 32–33. Leave to amend is denied as to these new theories. This action was filed more than four years ago, and relator has already filed three iterations of the complaint. Relator neglected to present these legal theories in any of his prior complaints and, in fact, voluntarily dismissed claims that were brought directly under Public Health Law Section 238-a and Education Law Section 6530(17). *See* July 5, 2022 Letter 3. Permitting relator to re-introduce at this late hour his allegations that defendants violated these state statutes—now through the lense of the False Claims Act and New York False Claims Act—would result in undue delay and undue prejudice. *See, e.g., Barrows v. Forest Labs., Inc.*, 742 F.2d 54, 58 n.11 (2d Cir. 1984).